Date recv'd:_____
PR#:_____
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APPLICATION FOR REVIEW
Human Research
Schedule I or Schedule II Controlled Substances

Research Advisory Panel of California

All applicable sections of the application must be completed within the form field provided. Please type or print legibly. Note that certain fields require supporting attachments. Incomplete fields or missing attachments will delay the application process.

A. TITLE AND DESCRIPTION OF STUDY
Attach copy of study protocol.

B. PRINCIPAL INVESTIGATOR
Attach copy of CV's of Principal Investigator & Sub Investigators.

NAME:

INSTITUTION:

MAILING ADDRESS:

DIRECT CONTACT PHONE #:

C. LOCATION WHERE STUDY WILL BE CONDUCTED

D. STUDY AND COMPARATOR DRUGS
List study and comparator drugs and dosages - attach monograph for each. Include placebo if applicable.

Study Drug	Dose Range(s)

E. SOURCE OF STUDY DRUGS

F. PLAN FOR STORAGE AND ACCOUNTABILITY OF STUDY DRUGS
If pharmacy based - storage and accountability plan not required - provide name and location of pharmacy.

G. PLANNED NUMBER OF SUBJECTS

H. STUDY DURATION FOR EACH SUBJECT

I. ANTICIPATED STUDY START-UP AND COMPLETION DATES

J. SOURCE OF FUNDING

K. CONSENT

Attach copy of informed consent to be used with study; along with copy of the California Research Subjects Bill of Rights.

L. NAME AND ADDRESS OF IRB; IRB REVIEW STATUS

If IRB approval already procured; attach documentation.

M. *If Applicable* - PROVISIONS FOR HANDLING OF MEDICAL EMERGENCIES

If study drug is being administered at an onsite research lab, office, clinic, or hospital setting, a description of provisions for handling any medical emergencies that might occur is required. Attach description.

N. *If Applicable* - PROVISIONS FOR DISPENSING OF TAKE HOME STUDY MEDS

If study requires subjects to "take home" single or multiple doses of study meds, a description of provisions for the dispensing and labeling of these medications is required. Attach description. If pharmacy based - dispensing and labeling description not required - provide name and location of pharmacy.

O. ACKNOWLEDGMENTS & SIGNATURE OF PRINCIPAL INVESTIGATOR

As a final step in completing this application, Principal Investigator acknowledges that, upon receipt of Panel approval, he/she will comply with all Panel requirements, including prompt reporting of study emergent study drug related SAE's, and presentation of the California Research Subjects Bill of Rights to each subject at onset of consenting process.

_____ _____

Signature Date